Some Environmental Studies Using Banked Tissues

Name of study	No. of samples	Type of sample	Endpoint
National Human Adipose Tissue Survey (NHATS)	12,000	fat tissues	pesticide residues
National Health and Nutrition Examination Surveys (NHANES)	20,000	blood	mostly nutrition
National Human Exposure Assessment Survey (NHEXAS)	about 950	blood, urine, hair, fingernail	metals, volatile organics, pesticides, PAHs
Breast and prostate cancer studies (Helzlsouer)	25,000	blood	organochlorines and breast cancer, cadmium and prostate cancer
Harvard University Physicians Study	15,000	blood	PAH biomarkers, gene metabolism and carcinogens
Uranium miner studies (Taylor)	52	squamous cell cancers	mutation in the *p53* tumor suppressor gene
Lung cancer study (Taylor)	25	asbestos-associated lung tumors	mutations in smoking-associated tumors
Aflatoxin and liver cancer study (Groopman)	18,000	serum and urine	interaction between aflatoxin and hepatitis B in liver cancer

to link human specimens with individuals, or that a new informed consent must be obtained every time a researcher studies a new gene.

In their rush to protect research subjects, says Caporaso, Steinberg and others are confusing the big risks to individuals of having a *BRCA1* breast cancer gene or *HNPCC* colon cancer gene with risks from metabolic polymorphisms that are insignificant from the standpoint of the individual, yet important to public health. "It would be farfetched to think that [genes for carcinogen-metabolizing proteins] would have health implications for families," says Everson. But the proposed standards would hamstring this research, says Schulte.

The standard of anonymity is impossible to achieve without dumbing information on each individual down to uselessness, some researchers say. It only takes a few pieces of information such as grade and stage of tumor, age at resection, race, and smoking habit to make possible a definitive identity, even if all links in the database have been cut. "As an example of anonymity," says Steinberg, " a set of such parameters should identify at least three people.

"Requiring consent for every new gene to be studied from a sample is untenable," asserts Caporaso, "in that it does not appear to serve either the individual's interest or those of science. The cost is prohibitive. If it's a population-based cohort . . . and you want to write to every person and say we are going to test a genetic marker, this is what it means: with a cohort of 100,000 people, the cost is conservatively in the millions."

But in dealing with human subjects, it is important to err on the side of caution, Steinberg asserts, alluding to the medical establishment's past paternalism. "We are the servants of the public. We have to be very sensitive to issues of importance to the public . . . and we have to deal with their perception of risk."

The *JAMA* authors also recommended "enactment of more general legislation to ensure that no person or institution be able to obtain access, even by court order or subpoena, to either the samples used in research or the specific results of research performed on such samples." Their reasoning was that "although protection may already be provided by certificates of confidentiality, sources are entitled to this higher level of protection in exchange for allowing their samples to be used for research."

The Office for Protection from Research Risks at NIH might develop its own guidance, and the new National Bioethics Advisory Commission being established by President Clinton could issue guidance, says John Miller, the office's deputy director. For the moment at least, such guidance remains the province of individual institutional review boards.

The controversy over informed consent has left those who bank on tissues holding their breath. Tissue banking has proven its value as a versatile method of studying the impact of environmental contamination on human health, and for contributing information for environmental policy-making. Questions such as deciding how to conduct a study, which tissues to collect, and how best to store them can be difficult to answer, but usually yield to creativity, hard work, and money. Researchers fear that current issues surrounding informed consent might not be nearly so tractable. How this controversy plays out will have a profound impact on a crucial area of environmental research.

David Holzman

ERRATA

The second paragraph of the second column on page 23 of the article *The Attack of Asthma* in the January 1996 issue of *EHP* (104:1) mistakenly attributes statistics about Puerto Rican children and asthma to the *New York Times*. The information is taken from an article that appeared in the April 1993 issue of the *American Journal of Public Health* (83:4), entitled Reported Asthma among Puerto Rican, Mexican-American, and Cuban Children, 1982 through 1984. The statistics were also incorrectly identified as the rates of asthma among Puerto Rican, Mexican-American, Cuban, black, and white children between 1982 and1984. They should have been identified as the percentages of children who have ever had asthma. Also in this *EHP* article, the date at the bottom of the first column on page 23 mistakenly reads "between 1976 and 1908." The sentence should read "1980."